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Sections that should be included in the grant application that you will prepare for the APS Young Investigator Colloquium

- 1. **Abstract:** max 30 lines
- 2. Specific aims (approx. 0.5 page),
- 3. **Significance and innovation** (1 to 1.5 pages), includes background and corresponds to part 2 and 3 of the 'research plan' (see guidelines below)
- 4. **Preliminary data** (1 page); see guidelines part 4 of the research plan ("approach").
- 5. **Methods including a data analytic plan** (1-1.5 pages), see part 4 of the research plan (section called "approach").
- 6. **Team of investigators and environment** (i.e., why you, why other team members, unique or essential infrastructure and facilities available to you; 0.5 pages). This is typically included in part 4 of the research plan ("approach") although elements may shine through elsewhere, e.g., in innovation, preliminary data, and methods. See guidelines below.

Format and suggestions for your application, based on the NIH guidelines

You may deviate from the guidelines presented below, but they are deemed helpful when you are planning a NIH application. This guide is organized according to the major sections of the SF 424 (or PHS398) Grant Application, and copied in part from a summary guide provided by the NIH (http://deainfo.nci.nih.gov/extra/extdocs/gntapp.pdf). If you are planning to submit to the NIH, it is recommended to have a look at the original instructions and related documents. It is worthwhile to check if your application fits a Funding Opportunity Announcement (FOA), specific Request for Applications (RFA) or Program Announcements (PA). For information on unsolicited applications see also: http://grants1.nih.gov/grants/guide/parent_announcements.htm#more

Typesetting

Use an Arial, black font color, and a font size of 11 points or larger. Use standard paper size (8 $\frac{1}{2}$ " x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins.

(see also: http://grants.nih.gov/grants/writing application.htm)

Abstract

Members of the Study Section who are not primary reviewers may rely heavily on the abstract to understand your application. Consider the significance and innovation of the research proposed when preparing the Project Summary. The Project Summary must be no longer than 30 lines of text and include:

- a brief background of the project;
- specific aims, objectives, or hypotheses;
- the significance of the proposed research and relevance to public health;
- the unique features and innovation of the project;
- the methodology (action steps) to be used;
- expected results; and
- description of how your results will affect other research areas.

Suggestions

- Avoid describing past accomplishments and the use of the first person.
- Write the abstract last so that it reflects the entire application.
- Remember that the abstract will be used for purposes other than the review, such as to provide a brief description of the grant in annual reports, presentations, and dissemination to the public.

Background and research plan

The sections "aims", "significance and innovation" "preliminary data" "methods including a data analytic plan" "team of investigators and environment" would fall under this heading (Background and Research plan) when you would write and NIH grant.

NIH has restructured the applications by aligning the structure and content with review criteria. This alignment will help ensure that both reviewer and applicant expectations coincide for a more efficient and transparent application process. The Research Strategy/Plan is now organized into three sections: **Significance, Innovation, and Approach**. For an application with multiple Specific Aims, the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or address Significance, Innovation and Approach for all of the Specific Aims collectively

Research plan, part 1: Specific aims

The purpose of the specific aims is to describe concisely and realistically the goals of the proposed research and summarize the expected outcome(s), including the impact of the proposed research will exert on the research fields involved.

The specific aims should cover:

- broad, long-term goals;
- the specific objectives and hypotheses to be tested;
- summarize expected outcomes; and
- describe impact on the research field.

Suggestions:

- This is the most important page of the entire application since it may be the only section the unassigned reviewers read to understand approach, impact, and innovation.
- Generally, the Specific Aims section should begin with a brief narrative describing the long-term goals
 or objectives of the research project and the hypothesis to be tested. This is followed by a numbered
 list of the Aims.
- List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create
 a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a
 critical barrier to progress in the field, or develop new technology.
- Make sure your specific objectives or hypothesis are clearly stated, are testable
- Be as brief and specific as possible and don't be overly ambitious. A small, focused project is generally better received than a diffuse, multifaceted project.
- Focus on aims where you have good supporting preliminary data and scientific expertise.
- Include a brief statement of the overall impact of the research studies.

Research plan, part 2: Significance

The Significance section replaces the previous "Background and Significance" section.

The Significance section should explain the importance of the problem or describe the critical barrier to progress in the field that is being addressed. Explain how the proposed research project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

It should cover:

- the state of existing knowledge, including literature citations and highlights of relevant data;
- rationale of the proposed research;
- explain gaps that the project is intended to fill; and
- potential contribution of this research to the scientific field(s) and public health.

Suggestions:

- Make a compelling case: Why is the topic important? Why are the specific research questions important? How are the researchers qualified to address these?
- Avoid citing outdated research. Use citations not only as support for specific statements but also to
 establish familiarity with all of the relevant publications and points of view. Your application may well
 be reviewed by someone working in your field; don't leave them out
- Highlight why research findings are important beyond the confines of a specific project i.e., how can
 the results be applied to further research in this field or related areas.
- Clearly state public health implications.
- Show that the objectives are attainable within the stated time frame and include a time frame for each specific aim.
- Stress any innovations in experimental methods

Research plan, part 3: Innovation

Explain how the application challenges and seeks to shift current research or clinical practice paradigms. Describe and explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

The innovation section should include the following:

- Explain why concepts and methods are novel to the research field.
- Focus on innovation in study design and outcomes.
- Summarize novel findings to be presented as preliminary data in the Approach section.

Suggestions

- Describe how the application differs from current research or clinical practice paradigms.
- Provide a careful review of the current literature to support the innovative methodologies, approaches, or concepts of your research.
- Demonstrate familiarity with novel methodologies by citing your publications or your collaborator's publications.

Research plan, part 4: Approach

This section is crucial to how favorably an application is reviewed. The purpose of the approach section is to describe how the research will be carried out..

Content: The research design and methods section should include the following:

- PI's preliminary studies, data, and experience relevant to the application and the experimental design;
- the overview of the experimental design;
- a description of methods and analyses to be used to accomplish the specific aims of the project;
- a discussion of potential difficulties and limitations and how these will be overcome or mitigated;
- expected results, and alternative approaches that will be used if unexpected results are found;
- a projected sequence or timetable (work plan);
- if the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work;
- a detailed discussion of the way in which the results will be collected, analyzed, and interpreted;
- a description of any new methodology used and why it represents an improvement over the existing ones;

Suggestions

- 1. Number the sections in this part of the application to correspond to the numbers of the Specific Aims.
- 2. Preliminary data may be included before the Specific Aims sections. Alternatively, integrate preliminary data with the methods description for each Specific Aim. Preliminary data can be an essential part of a research grant application and helps establish the likelihood of success of the proposed project.
- 3. Avoid excessive experimental detail by referring to publications that describe the methods to be employed. If at all possible publications cited should be by the applicants: citing someone else's publication establishes that you know what method to use, but citing your own (or that of a collaborator) establishes that the applicant personnel are experienced with the necessary techniques.
- 4. If relevant, explain why one approach or method will be used in preference to others. This establishes that the alternatives were not simply overlooked. Give not only the "how" but the "why."
- 5. If employing a complex technology for the first time, take extra care to demonstrate familiarity with the experimental details and potential pitfalls. Add a co-investigator or consultant experienced with the technology, if necessary.
- 6. Explain how the research data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
- 7. Develop alternative strategies for potential problems.

Appendix

NIH Peer Review Criteria

(see also: http://grants.nih.gov/grants/writing application.htm):

In their written critiques, reviewers will comment on each of the following criteria to evaluate the likelihood that the proposed research will have a substantial impact on the pursuit of one or more of these goals. The overall score is assigned based on the reviews for each of these criteria. Reviewers are instructed to keep the five review criteria in mind; however, the final priority score they assign is more likely to reflect a judgment of overall merit.

NOTE: These are general review criteria for evaluating unsolicited research project grant applications. NRSA fellowship award, career development award, and specific funding opportunity announcements (FOAs) may have different or additional special review criteria. Applicants should familiarize themselves with the review criteria by which their application will be evaluated.

- 1. Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- 2. Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
- 3. **Innovation.** Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?
- 4. Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?
- 5. **Environment.** Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?